



Agricultural Marketing Service

[Doc. No. AMS-FGIS-22-0019]

Process for the Evaluation of Technology for Official Grain Inspection

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) currently evaluates and approves technology for use in official grain inspection on a case-by-case basis. AMS proposes a new internal process that is meant to facilitate the introduction of new and improved inspection technology that promotes competition and transparency. AMS is seeking public comment on the proposed process.

DATES: Comments must be received by [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Additional technical information on the evaluation process can be found in the “Procedure and Submission Guidelines for the Evaluation of Technology for Official Grain Inspection” at

<https://www.ams.usda.gov/sites/default/files/media/FGISUserGuideforManufacturers.pdf>

Interested persons are invited to submit written comments concerning this Notice using either of the following procedures:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. You can access this Notice and instructions for submitting public comments by searching for document number, AMS-FGIS-22-0019.
- *Mail:* Dr. Timothy D. Norden, National Grain Center, 10383 N. Ambassador Drive, Kansas City, Missouri 64153.

All submissions received must include the docket number AMS-FGIS-22-0019.

All comments received will be included in the record and will be posted without change, including any personal information provided. Comments will be made available for public inspection at the above address during regular business hours or via the at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Timothy D. Norden, Chief Scientist, Technology and Science Division, Federal Grain Inspection Service, AMS, USDA; Telephone: (816) 702-3803, or Email: Timothy.D.Norden@usda.gov.

SUPPLEMENTARY INFORMATION: AMS provides grain inspection services under the authority of the United States Grain Standards Act (7 U.S.C. 71–87k) (USGSA), as amended, and the Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627), as amended. USGSA at 7 U.S.C. 74 states that the primary objective of the United States standards for grain is to certify the quality of grain as accurately as practicable and to accommodate scientific advances in testing and new knowledge concerning factors related to, or highly correlated with, the end-use performance of grain. The primary focus of the proposed Inspection Technology Evaluation (ITE) Process is on the need and suitability of the technology for official grain inspection. Below is a description of the proposed ITE Process.

“Technology” refers to instrumentation, equipment, and the associated methods for measuring grain quality factors. “Factor” means a measurable grain quality attribute. This evaluation process does not apply to the research and development effort before the technology is deemed fit-for-purpose; that is, the instrument or method has already been developed so that it generates factor-specific results with sufficient accuracy for official grain inspection.

ITE Process Description

The ITE process starts with the submission of a written proposal by a manufacturer of technology for a specific inspection factor. Manufacturers provide an overview of the technology for which they seek approval. This overview should describe the technology solution, indicate to which grains and inspection factor, or factors the technology applies, and the steps the technology uses to analyze a sample. The proposal should address six criteria, which will form the basis of the initial evaluation. These criteria are: 1) need; 2) accuracy; 3) quality control; 4) automation; 5) testing time; and 6) testing cost.

An AMS review team conducts an initial evaluation of the proposal to determine if it meets these criteria. When the review team completes the initial evaluation, AMS decides whether to accept the proposal. This decision is documented and communicated to the manufacturer. If a proposal is not accepted, the manufacturer is informed of the specific deficiencies and the requirements for resubmission. If accepted, the proposal enters a queue, and the manufacturer is notified and provided with an estimate for the start date along with various factors that may affect the length of the evaluation process.

The remaining steps of the evaluation process focus on validating the performance of the submitted technology using AMS' developed criteria or specifications for the specific inspection factor. This allows for refinement of the initial review criteria to account for specific inspection needs and for a statistically sound evaluation of accuracy of the technology. If not already established, AMS develops performance criteria and specifications and determines whether a Federal Register notice is needed to finalize the criteria.

With established performance criteria and specifications, AMS requests that the manufacturer provides information and data supporting the criteria and specifications. When all requested information has been submitted and accepted, AMS conducts an independent verification that focuses on accuracy. AMS will also determine if the

submitted technology delivers results that are equivalent to currently approved technology. If this process shows that the technology is accurate and it passes the equivalence test, AMS notifies stakeholders and provides them with the implementation plan. If AMS is unable to verify the accuracy or the technology is not equivalent, the manufacturer is notified of the deficiencies and the requirements for resubmission.

If AMS approves the technology, an AMS certificate of conformance (COC) is issued that allows for use in official grain inspection. If any alterations to the technology are made that could affect measurement results, the manufacturer should inform AMS in writing to determine the significance. In addition, if the manufacturer finds that the technology is not meeting AMS performance criteria, they should immediately inform AMS. Failure to inform AMS, may result in cancellation of the COC.

Evaluation Criteria

Need. AMS assesses the need criterion through a review of the manufacturer-provided information, input from stakeholders including the Grain Inspection Advisory Committee, and from internal information. AMS evaluates the demand for the testing technology from AMS customers and stakeholders and compares the demand to the costs of providing the testing service, including standardization, calibration, and quality control efforts. AMS recommends that manufacturers provide information from a market assessment of the technology that supports this demand. For existing inspection factors, a successful technology should be compatible with existing official procedures such as subsample size requirements. For a test factor with an existing single approved instrument model, a successful new instrument should offer an added benefit to official inspection and provide results in terms of accuracy that are equivalent to, or better than the currently approved instrument model. If pertinent, manufacturers should provide national or international regulatory requirements the technology addresses. This may include, but is not limited to, maximum levels for toxic substances.

Accuracy and Quality Control. Manufacturers should provide relevant data that support both the accuracy and quality control criteria. Manufacturers and other interested parties are encouraged to review the specific requirements and additional technical information at [insert hyperlink to technical document].

Automation. If the technology generates an electronic result, the manufacturer should provide procedures for automatic data capture and the method to modify the output.

Testing Time. Manufacturers should provide the estimated testing time required from sample receipt to final result. The testing time will be assessed by comparison to existing or similar technologies. Longer testing times should be justified by providing a significant advantage over existing technology.

Testing Cost. The manufacturer should provide itemized cost estimates for the technology, maintenance, consumables, and all materials and equipment needed to perform the test. AMS evaluates the estimated costs of the recommended quality control, calibration, and standardization procedures. The testing cost is compared to existing or similar technologies. Higher testing costs should provide significant advantages over existing technologies.

Melissa R. Bailey,

Associate Administrator,

Agricultural Marketing Service.

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